

**A workforce in Crisis: Why the Cellular Therapy Field is Running Out of Qualified
Technologists**

Part 1 of a three-part series: Closing the Gap: Building a Cellular Therapy Workforce for the
Future

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Running Title: Cellular Therapy Workforce Crisis

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Word Count: approximately 2,900 words (body text, excluding abstract and references)

Conflict of Interest Statement: The author declares no conflicts of interest.

Funding: No external funding was received for this work.

Submission Statement: This manuscript is submitted exclusively to Clinical Laboratory Science and has not been published previously or submitted concurrently to another journal. This Part 1 of a planned three-part series. Copies of Parts 2 and 3 are available upon request from the editorial office.

Abstract

The rapid expansion of cell and gene therapies has transformed the landscape of modern medicine, creating new treatment options for diseases once considered incurable. Yet behind every therapeutic milestone stands a specialized workforce, clinical laboratory scientists, cell processing technologists, and biomanufacturing professionals, whose contributions rarely receive comparable attention. As the number of FDA-approved cellular therapies continues to grow, a critical and largely unaddressed workforce shortage threatens the safe, sustainable delivery of these treatments. Traditional medical laboratory science and biotechnology education programs have not kept pace with the competency demands of cellular therapy environments, leaving a significant gap between what graduates know and what these roles require. This article examines the scope of the cellular therapy workforce shortage, its implications for patient safety and program sustainability, and why clinical laboratory scientists are uniquely positioned to close this gap if the profession builds the pathways to help them do so. Closing this gap will require coordinated workforce development strategies. Those strategies must connect academic institutions, healthcare systems, and the biotechnology industry around shared competency standards and scalable training models.

Abbreviations: FDA, United States Food and Drug Administration; CAR-T, chimeric antigen receptor T-cell; CLS, clinical laboratory science; MLS, medical laboratory science; GMP, good manufacturing practice; NAACLS, National Accrediting Agency for Clinical Laboratory Sciences; ASCP, American Society for Clinical Pathology; ASCLS, American Society for Clinical Laboratory Science; FACT, Foundation for the Accreditation of Cellular Therapy; AABB, Association for the Advancement of Blood and Biotherapies; ARM, Alliance for Regenerative Medicine; GAO, U.S. Government Accountability Office

Index Terms (MeSH): Cell-and Tissue-Based Therapy, Workforce, Laboratory Personnel;
Education, Professional; Clinical Competence

In 2017, the United States Food and Drug Administration (FDA) approved the first chimeric antigen receptor T-cell (CAR-T) therapy, ushering in a new era of personalized medicine. Since then, the number of approved cellular and gene therapies has grown steadily, with hundreds of additional candidates currently in clinical trials.¹ Each approval represents a scientific achievement and an operational demand. Before a CAR-T product reaches a patient, it must be collected, processed, quality tested, released, and administered by a team of trained professionals working within tightly regulated environments. These are not simple tasks, and they require a workforce with a unique blend of competencies spanning clinical laboratory science, cell biology, molecular diagnostics, biomanufacturing, and regulatory compliance.

The problem is that this workforce does not yet exist at the scale the field requires. Clinical laboratory scientists (CLSs) and medical laboratory scientists (MLSs) represent one of the most logical candidate pools for cellular therapy roles. Their foundational training in laboratory science, quality assurance, specimen processing, and regulatory compliance aligns directly with many of the operational demands of cellular therapy laboratories. Yet most CLS and MLS educational programs were designed for traditional diagnostic laboratory environments and have not been updated to reflect the competency demands of cell processing, gene therapy manufacturing, or good manufacturing practice (GMP) environments.² The result is workforce gap that is growing faster than existing educational systems can address.³ This article examines the scope of that gap, the factors that created it, and why the profession and organizations like American Society for Clinical Pathology (ASCP) and American Society for Clinical Science (ASCLS), have both the opportunity and the responsibility to lead the response.

The Growth of Cellular and Gene Therapy: A Workforce Demand Unlike Any Before

Cellular and gene therapies represent one of the most rapidly evolving sectors in biomedical science. The Alliance for Regenerative Medicine (ARM) reported that as of 2023, there were more than 1,000 active clinical trials in cell and gene therapy globally, with North America accounting for a significant share of that activity.⁴ The market itself is projected to reach tens of billions of dollars within the next decade, driven by approvals in oncology, rare genetic diseases, and autoimmune conditions.⁵ Unlike pharmaceutical manufacturing, which often relies on chemical synthesis at scale, cellular therapies are frequently patient-specific. Each unit must be processed individually, tracked through a complex chain of custody, tested for identity and viability, and released by qualified personnel.⁶ These steps must occur within narrow timeframes that are biologically determined, not logistically convenient.⁶ This individualized and time-sensitive nature of cellular therapy work creates workforce demands that are fundamentally different from those of conventional laboratory or pharmaceutical environments.

Stem cell transplant programs, which have operated for decades, provide a preview of these demands. Laboratories supporting hematopoietic stem cell transplantation have long relied on professionals with specialized knowledge of cell processing, cryopreservation, and sterility testing.⁷ The expansion of CAR-T therapies and other advanced cellular products has intensified and broadened these demands, extending them into hospital-based cell therapy laboratories, academic medical centers, and commercial biomanufacturing facilities alike.⁶ These programs illustrate both the operational complexity of cellular therapy work and the critical role that well-trained laboratory professionals play in sustaining it. The workforce demands associated with CAR-T and other emerging therapies are not an extension of existing laboratory practice but represent a distinct and growing occupational category that requires purposeful educational investment.

The Workforce Gap: What We Know and What We Are Missing

Despite growing demand, to the author's knowledge no national registry or comprehensive workforce survey yet exists that specifically tracks the cellular therapy technologist workforce as a distinct category. This absence of data itself is a problem. It makes it difficult to quantify the shortage, advocate for funding, or design targeted educational interventions. What is known comes from a combination of accreditation body reports, industry workforce analyses, and the direct observations of laboratory directors and program managers who struggle to fill open positions.² The lack of a dedicated tracking mechanism also means that policymakers and academic institutions lack the evidence needed to justify investment in new training programs. The Foundation for the Accreditation of Cellular Therapy (FACT) accredits cellular therapy programs across North America and internationally, and its standards require that programs maintain personnel with defined and demonstrable competencies.⁸ When programs cannot recruit or retain staff who meet those requirements, accreditation compliance is at risk. This makes the workforce shortage not only an operational problem but a regulatory one, with direct consequences for program viability and patient access to treatment. AABB, which also provides standards for cellular therapy services, similarly requires trained personnel as a core requirement for accreditation compliance.⁹ Neither organization was designed to build the workforce pipeline that their standards assume exist. That pipeline must be built by academic institutions, professional societies, and industry partners working in concert.

The consequences of this gap are not abstract. Laboratory directors report difficulty recruiting qualified staff, extended vacancy periods for specialized positions, and the need to invest heavily in on-the-job training for new hires who arrive without the specific competencies cellular therapy environments demand.² Accreditation bodies and laboratory directors have informally

documented these pressures, though comprehensive national data on program-level impact remains limited. The staffing challenges facing cellular therapy programs are not isolated incidents. They reflect a systemic misalignment between the supply of trained professionals and the operational needs of a rapidly growing field.

Clinical Laboratory Scientists: A Workforce Ready to Step Forward

Among the various professional groups that could help close the cellular therapy workforce gap, clinical laboratory scientists are uniquely positioned to do so. The competency foundation of CLS and MLS training includes analytical thinking, quality control, specimen integrity, regulatory compliance, and laboratory safety. These competencies map directly into the operational requirements of cellular therapy environments. CLSs are already trained to work in regulated laboratory settings, to follow complex protocols with precision, and to apply critical thinking when results or processes fall outside expected parameters.

This alignment is not incidental; it reflects a shared scientific and regulatory foundation that distinguishes CLSs from other candidate pools.

Cellular therapy laboratories require exactly these skills. Cell processing, flow cytometry, sterility testing, chain of custody documentation, and GMP compliance are not foreign concepts to a CLS with the right additional training. They are extensions of competencies already developed. What is missing is not the foundational capability but the specialized overlay. That overlay includes knowledge of cell biology applications, familiarity with GMP environments, understanding of regulatory pathways for advanced therapies, and hands-on experience with cell culture and processing techniques.

This is not merely a theoretical alignment. The competency overlap between CLS training and cellular therapy requirements is supported by peer-reviewed workforce analyses.^{10,11} It is

reasonable to expect that professionals with this foundation would require less time to reach proficiency in cellular therapy roles than candidates without it, provided that targeted supplemental education is available to bridge the remaining gap. The challenge is that this supplemental education has largely been pursued informally, through on-the-job training, individual professional development, or occasional workshops. Structured and standardized educational pathways capable of delivering this training at scale do not yet widely exist.¹² For CLSs themselves, cellular therapy represents a meaningful career expansion opportunity. Traditional diagnostic laboratory roles, while essential, can feel limiting for professionals seeking to apply their scientific training in emerging, high impact areas. Cellular therapy offers work at the frontier of medicine, in an environment where laboratory science expertise directly contributes to patient outcomes that were not possible a decade ago. These roles carry professional significance that extends beyond the bench. The profession has an obligation to make these pathways visible, accessible, and clearly defined.

Why Education Has Not Kept Pace

The lag between workforce demand and educational response is not unique to cellular therapy. It is a recurring pattern in health professions education when new clinical domains emerge faster than accreditation standards and curriculum frameworks can adapt. In many fields, this lag eventually self-corrects as professional organizations respond and credentialing bodies update their standards.¹³ However, cellular therapy presents specific challenges that have made this lag particularly acute and that are unlikely to resolve without deliberate intervention. Understanding those challenges is essential to identifying the right solutions.

First, cellular therapy sits at the intersection of multiple disciplines, including clinical laboratory science, biotechnology, pharmaceutical manufacturing, and clinical medicine, and none of those

disciplines fully claims it. MLS and CLS programs are accredited through the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS), whose standards appropriately focus on traditional diagnostic laboratory competencies.¹² Biotechnology programs, which exist at both the community college and university level, tend to focus on research techniques or pharmaceutical manufacturing without integrating the clinical regulatory environment. Neither pathway fully prepares graduates for the specific demands of a cellular therapy laboratory or manufacturing facility. The result is a field with no natural academic home and no clear educational pipeline.

Second, the cellular therapy field itself has evolved so rapidly that even practitioners within it are continuously updating their knowledge and skills.^{10,11} Designing educational curricula for a moving target requires not only curricular agility but also strong connections between academic programs and industry and clinical partners. Those partners are essential because they can inform what competencies are needed at any given time. Without those relationships, academic programs risk teaching content that is already outdated by the time students graduate. Sustained, structured collaboration between educators and practitioners is not optional in this field; it is a prerequisite for relevant training.

Third, the absence of a defined credential or certification pathway for cellular therapy technologists means there is no external standard driving educational programs to develop relevant content. When a licensure exam or national certification defines what graduates must know, educational programs have a clear and externally validated target for curriculum development.¹³ In cellular therapy, no equivalent standard currently exists. This leaves programs without a clear target and students without a nationally recognized credential to pursue. Without

a defined credential, employers also lack a reliable signal of competency, which further complicates hiring and perpetuates the cycle of on-the-job remediation.

The Case for a Coordinated, Multi-Stakeholder Response

It was in recognition of these compounding challenges that the field must move toward a deliberately coordinated response. That response must bring together academic institutions, healthcare systems, professional societies, and biotechnology industry partners. The shared goal is to develop the cellular therapy workforce through education, training, and leadership development. This kind of coordination is not unprecedented in health professions education,¹³ but it must be intentional and sustained to be effective. Without it, individual programs will continue to work in isolation, duplicating effort and producing inconsistent results.

No single institution, program, or professional society can address the cellular therapy workforce gap alone. The problem is systemic and spans educational pipelines, credentialing frameworks, regulatory environments, and professional identity. What is needed is a convening structure that aligns the efforts of diverse partners around shared competency standards, scalable training models, and sustainable workforce development strategies. Professional organizations such as ASCP and ASCLS are well positioned to initiate and sustain this kind of coordination, given their established roles in workforce advocacy, accreditation engagement, and professional development across the laboratory science field.^{2,12}

Such coordination must be informed not by theory alone but by the operational realities of laboratories and manufacturing facilities navigating these challenges every day. The professionals working at the intersection of cellular therapy and laboratory science are uniquely positioned to define what competencies are needed, what training models are feasible, and what partnerships are required to build a sustainable workforce pipeline. Their perspective must be

centered on any serious workforce development effort. Academic institutions, in turn, must be willing to adapt curriculum structures and forge the clinical and industry relationships that make applied training possible. The conditions for progress exist; what is needed is the organizational will to bring them together.

Conclusion

The cellular therapy workforce shortage is not a distant threat, it is a present reality that is already affecting program capacity, patient access, and the ability of the field to sustain its remarkable pace of innovation. CLSs have both the foundational training and the professional motivation to help close this gap. However, the educational pathways, credentialing frameworks, and institutional partnerships needed to support their transition into cellular therapy roles remain underdeveloped. Addressing this requires not just awareness but coordinated action from academic institutions, professional organizations, and clinical and industry partners.

The good news is that solutions exist and some are already working. Part 2 of this series will examine emerging educational models, including interdisciplinary certificate programs that are demonstrating how the right curriculum design can produce cellular therapy-ready graduates in a fraction of the time previously thought necessary. These models offer proof of concept that the gap is bridgeable with the right investment and design. Part 3 will address the policy and credentialing landscape, making the case for national standards and the role that professional societies like ASCP and ASCLS must play in establishing them. Together, these articles aim to move the conversation from diagnosis to action.

For now, the most crucial step is acknowledging the scope of the problem clearly and publicly. The field of cellular therapy will not reach its potential, and patients will not gain full access to its benefits, without a skilled, prepared, and growing technologist workforce. Building that

workforce begins with the profession's willingness to name the gap and commit to closing it. It also requires honesty about the structural barriers that have allowed the gap to persist for as long as it has. The cellular therapy field has achieved extraordinary scientific milestones; building the workforce to sustain those milestones is the next essential task.

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This is Part 1 of a three-part series. Part 2: Building the Bridge: Interdisciplinary Education Models That Are Already Working. Part 3: Credentialing the Cellular Therapy Technologist: The Case for National Standards and a Unified Framework.